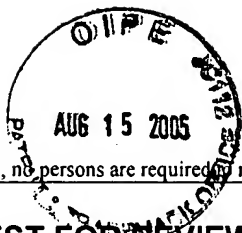



Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)

Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

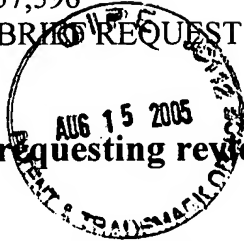
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional): 01-531	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>8/10/05</u> Signature <u>Martoni Scamati</u> Typed or printed name <u>MARTONI SCAMATI</u>		Application Number 10/057,596	Filed 01/24/2002
		First Named Inventor : Douglas C. Shepard	
		Art Unit: 1615	Examiner: Gollamudi S. Kishore
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the			
<input type="checkbox"/> applicant/inventor.		 Signature	
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)		Keum J. Park Typed or printed name	
<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>42,059</u>		<u>908-518-7700</u> Telephone number	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		<u>August 10, 2005</u> Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Reasons for requesting review:

- For a reference or combination of references to support a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion nor motivation to make the necessary modification of the teaching of the reference or references combined to result in the pending claims; (2) there must be a reasonable expectation of success; and (3) the prior art reference must teach or suggest all the claim limitations. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *see* MPEP § 2142-2143; *see In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q. 1596, 1598-99 (Fed. Cir. 1988).
- **In the Final Rejection mailed April 15, 2005**, Claims 1, 13-16 and 19-24 were rejected under 35 U.S.C. 103(a) as being unpatentable over any one of (a) Hendrickson, (b) Antwerp and (c) Forster taken alone. The rejection is clearly erroneous because none of these references discloses an enzyme (on an article) disposed within a polymer matrix, as required by the claims, or the specific class of block copolymers claimed. (*See* Response filed 6/15/05, page 6, lines 7-11). Further, there is no suggestion in these references to modify the enzymes and coatings of these reference to result in the pending claims, either singly or in combination or that there is any reasonable expectation of success that combining the teachings will result in the claimed polymer articles.
- **Applicant's Response filed 6/15/05** pointed out deficiencies evident in the primary references, which the Examiner apparently did not appreciate.

- Applicant pointed out that none of the references teaches an enzyme "within" a polymer matrix, as required by the claims. (*See* Response filed 6/15/05, page 6, lines 10-11). Rather, the Hendrickson reference teaches enzymes immobilized on a fibrous support and "coated" with a polymer. The Antwerp reference teaches an enzyme bound directly to a catheter and then "coated" with a starch based encapsulating coating. The Forster reference teaches an

enzyme coated (immobilized) directly on a vascular prosthesis and no polymeric matrix below, around or above the enzyme. (*See* Response filed 6/15/05, page 6, lines 12-20).

- Applicant explained, in detail, the structural significance of Applicant's claimed polymeric matrix article and how the references do not teach this polymeric matrix article. Further, Applicant explained how the structure allows the claimed function of "diffusion of enzymatic substrates into, and diffusion of enzymatic products out of the matrix." (*See* Response filed 6/15/05, page 6, line 21 to page 7, line 4).
- No explanation for the conclusion of obviousness was presented by the Examiner. Nothing in these references provides any motivation or suggestion to modify the disclosed enzyme coatings to result in the claimed articles or that there is a reasonable expectation of success of producing the claimed articles from these teachings. The Examiner failed to show how "immobilization of enzymes" of the cited references renders the claimed polymer matrix with enzymes disposed within the matrix obvious. The Examiner also failed to show how the cited references teach or suggest the claimed functional limitations regarding the "diffusion" action of the enzymatic substrates.

● **The Examiner's Advisory Action mailed July 5, 2005**, again, offered no explanation of how the references, which teach immobilized enzyme coatings, either in form function, suggest the claimed articles or provide motivation or suggestion to make the necessary modification of the teachings of the references to result in the claimed polymer matrix having enzymes disposed within the matrix.

- Rather, the Advisory Action states that "...[t]he primary references clearly teach the immobilization of enzymes on devices although not using the claimed block copolymers. The motivation to use claimed polymers in these devices can be derived from the secondary reference of Pinchuk who teaches

the advantages of these polymers when implanted in vivo.” (*See* Advisory Action dated 7/5/05).

● **In the Final Action dated 4/15/05**, the Examiner rejected the Claims 1, 13-16, and 19-24 over (a) Hendrickson, (b) Antwerp and (c) Foster alone, or in combination, further in view of Pinchuk. This rejection is also clearly erroneous. The conclusion of obviousness was simply that it would have been “obvious to use” the polymers of Pinchuk in the devices of (a), (b) or (c) because “Pinchuk teaches that these block copolymers are biostable and crack-resistant when implanted in vivo.” (*See* Final Rejection dated 4/15/05, page 3, paragraph 4).

● **In Applicant’s Response dated 6/15/05**, Applicant pointed out the following deficiencies in Pinchuk:

- Pinchuk discloses implants or prostheses produced from a class of polymers similar to and possibly inclusive of those recited in the rejected claims. However, Pinchuk does not explicitly teach prosthesis coated with these polymers. The only mention of enzymes in the Pinchuk disclosure is that the articles produced from those polymers are resistant to enzymatic destruction. (*See* Response dated 6/15/05, page 7, lines 5-15).
- None of the references, including Pinchuk, discloses enzymes as an actual part of the article, wherein enzymes are within a matrix of the relevant polymers. Thus, there is no motivation or suggestion to combine the references. In addition, if (a), (b) or (c) were combined with Pinchuk in the manner postulated by the Examiner, the claimed invention would not result. (*See* Response dated 6/15/05, page 7, lines 5-15).

● **In the Advisory Action dated 7/5/05**, the Examiner reiterated that it would have been obvious to use the Pinchuk polymers in the devices of primary references (a), (b) or (c) because “Pinchuk teaches the advantages of these polymers when implanted in vivo.” (*See* Advisory Action dated 7/5/05). The Examiner did not provide any additional

comments supporting a *prima facie* case of obviousness with respect to the underlying primary references.

- **In the Final Rejection mailed 4/15/05**, the Examiner rejected claims 1, 11-16, 19-24 and 27 under 35 U.S.C. 103(a) as being unpatentable over Sivan in view of Pinchuk. This rejection is also clearly erroneous because Sivan does not disclose either the claimed copolymers or teach the claimed enzyme disposed within a polymeric matrix.

- **In Applicant's Response dated 6/15/05**, the defects of Sivan were explained in considerable detail.

- Sivan discloses a medical device with an enzyme attached directly to that device. The enzyme may be entrapped within a polymer hydrogel. However, the enzyme is one of the monomers from which the hydrogel is formed; it is not disposed within a specifically recited polymer matrix, as in the rejected claims. Furthermore, the monomers with which the enzyme is copolymerized in Sivan would not meet the terms of the copolymer recited in the rejected claims and are not even remotely similar. Thus, combination of this reference with Pinchuk could not establish a *prima facie* case of obviousness in light of the above cited prior decisions.

- **In the Advisory Action dated 7/5/05**, nothing further was provided by way of explanation.

- **In the Final Rejection dated 4/15/05**, Claims 17 and 18, which recite specific mechanisms by which the enzyme (disposed within the matrix) bonds to the surface of the article, were rejected under 35 U.S.C. 103(a) as being unpatentable over Sivan in view of Pinchuk and Applicant's acknowledgement of the prior art. This rejection is also clearly erroneous.

- **Applicant's Response filed 6/15/05** explained that the types of bonding recited in those dependent claims were generally known, but that they did not remedy the defects in the basic rejection. Sivan does not disclose either the claimed copolymers or teach the claimed enzymes disposed within a polymeric matrix. (See Response dated 6/15/05, page 7, line 21 to page 8, line 11).
- **In the Advisory Action dated 7/5/05**, no mention was made of this rejection.
- Reconsideration and withdrawal of the above discussed rejections, which are clearly erroneous, are requested.